

Exhibit 19

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 20-F

(Mark One)

- ☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
or
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016
Or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Or
☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report

For the transition period from to

Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, Executive Vice President Legal Affairs and General Counsel
54, Rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:

Name of each exchange on which registered:

American Depositary Shares, each representing one half of one ordinary
share, par value €2 per share
Ordinary shares, par value €2 per share
Contingent Value Rights

New York Stock Exchange
New York Stock Exchange (for listing purposes only)
NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2016 was:

Ordinary shares: 1,292,022,324

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐.

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. YES ☐ NO ☒.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

International Financial Reporting Standards as issued by

the International Accounting Standards Board ☒

Other ☐

U.S. GAAP ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.
Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒.

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Orange Book listed patents. Having settled with all but two generic manufacturers, Sanofi went to trial against Sandoz and Watson in early June 2016 alleging infringement of US patents 8,318,800 (formulation) and 8,410,167 (method of use). In August 2016, the Court ruled in Sanofi's favor finding the '800 patent infringed and the '167 patent valid and infringed by both Sandoz and Watson. In September 2016, Sandoz and Watson filed a Notice of Appeal to the Court of Appeals for the Federal Circuit.

On October 13, 2015, Sanofi amended its complaint against Lupin to include US Patent 9,107,900 which was listed in the Orange Book in September 2015. In December 2015, Sanofi filed separate patent infringement actions against six of the other defendants based on this patent. Having settled with all but three generic manufacturers, Sanofi is scheduled to go to trial on the '900 patent in April 2017 against Sandoz, Watson and Lupin.

• ***Genzyme Myozyme®/Lumizyme® Patent Litigation (United States)***

BioMarin filed petitions with the PTAB (Patent Trial and Appeal Board) requesting institution of an IPR (Inter Partes Review) of the patentability of all claims of US Patent No. 7,351,410 and all but one claims of US Patent No. 7,655,226 regarding Myozyme®/Lumizyme®. Those petitions were granted. In February 2015, the PTAB ordered inter alia that claim 1 of the '410 patent and that claims 1 and 3-6 of the '226 patent are determined to be un-patentable. Genzyme filed a Notice of Appeal to the Federal Circuit in April 2015. The United States Patent and Trademark Office (USPTO) filed a Notice of Intervention in September 2015.

In June 2016, the Federal circuit upheld the PTAB decision ordering inter alia that claim 1 of the '410 patent and that claims 1 and 3-6 of the '226 patent are determined to be un-patentable. Genzyme filed a Petition for Rehearing in August 2016. The Federal Circuit denied Genzyme's Petition in September 2016.

• ***Genzyme Aubagio® Patent Litigation (United States)***

Aubagio® is covered by three Orange Book listed patents: US 6,794,410, US 8,802,735, and US 9,186,346. In November/December 2016, a number of generic manufacturers separately notified Sanofi Genzyme that they had filed ANDA applications for Aubagio® with Paragraph IV certifications challenging the '410, '735 and '346 patents. Sanofi Genzyme filed suit against each ANDA filer within 45 days of receipt of each notification in the US District Court for the District of Delaware. The associated 30-month stay of FDA approval on each ANDA expires on the earlier of (i) March 12, 2020 or (ii) a court decision in favor of one of the generics manufacturers.

• ***Dupixent™ (dupilumab)-related Patent Opposition and Revocation (Europe)***

Immunex Corporation, an Amgen affiliate, is the registered proprietor of European Patent number EP2292665. The claims of this patent relate to, among other things, human monoclonal antibodies that are capable of inhibiting IL-4 induced biological activity and which compete with one of

four reference antibodies for binding to a cell that expresses human IL-4R. In April 2016, Sanofi and Regeneron each filed an opposition in the European Patent Office against EP2292665, seeking its revocation on the basis that, inter alia, the claims are overly broad. In September 2016, Sanofi also filed a civil action in the U.K. High Court (Chancery Division/Patents Court) seeking revocation of the U.K. designation of EP2292665 on similar grounds. In January 2017, at the joint request of Sanofi and Immunex, the U.K. High Court ordered that the revocation action be stayed pending the final determination of the pending European Patent Office opposition proceedings.

Government Investigations and Related Litigation

From time to time, subsidiaries of Sanofi are subject to governmental investigations and information requests from regulatory authorities inquiring as to the practices of Sanofi with respect to the sales, marketing, and promotion of its products.

In December 2013, Genzyme entered into a settlement agreement to resolve civil claims arising out of the investigation into promotional practices of Septrafilm® and paid in that respect approximately \$23 million. As part of this settlement, and as part of the settlement entered into by Sanofi US in December 2012 relating to civil claims arising out of an investigation into sampling of its former product Hyalgan® for which Sanofi US paid \$109 million, the companies entered into a Corporate Integrity Agreement ("CIA") with the Office of the Inspector General of the United States Department of Health and Human Services in September 2015. Also in September 2015, Genzyme entered into a Deferred Prosecution Agreement ("DPA") with the US Department of Justice and paid in that respect approximately \$33 million to resolve the Septrafilm® matter completely. The CIA and the DPA are currently in effect.

In March 2016, Sanofi US received a civil investigative demand from the US Attorney's Office for the Southern District of New York requesting documents and information relating to contracts with, services performed by and payments to pharmacy benefit managers regarding Lantus® and Apidra® from January 1, 2006 forward. Sanofi US is cooperating with this investigation.

In June 2016, the United States declined to intervene in a False Claims Act action filed in Federal Court in New Jersey regarding the sale and marketing of and variability of response to Plavix®. Sanofi US is defending this and another False Claims Act action relating to Plavix® pending in the same court. Five State Attorney General actions (Hawaii, Louisiana, Mississippi, New Mexico and West Virginia) concerning the sale and marketing of Plavix® also remain pending.

In December 2016 and January 2017, two putative class actions were filed against Sanofi US and Sanofi GmbH in Federal Court in Massachusetts on behalf of direct-purchasers of Lantus® alleging certain antitrust violations.

In January 2017, the Minnesota State Attorney General's office issued a civil investigative demand calling for the production of documents and information relating to pricing